

## GCS CLINICAL TRIALS

Cancer	Title / Site #	Study	Treatment	Key Criteria	Miscellaneous Criteria	Status
<b>BREAST</b>						
<b>Breast NeoAdjuvant</b>	<b>Merrimack</b> MM-121-02-02-07  <b>Site #: 128</b>	<b>Neo-adj Phase II</b>  <b>Randomized 2:1</b>  <b>Group 1:</b> <b>ER + / Her 2 –</b>  <b>Group 2:</b> <b>Triple Negative</b>	<b>Arm A:</b> 2 wk run-in of MM-121 ( <b>Human Anti ErbB3 Antagonist</b> ) f/b 12 wks Paclitaxel & MM-121 f/b 8 wks Doxorubicin/Cyclophosphamide f/b surgery.  <b>Arm B:</b> 12 wks Paclitaxel alone f/b 8 wks Doxorubicin/Cyclo-Phosphamide f/b surgery.	<ul style="list-style-type: none"> <li>• Histological confirmation of ER positive, HER2 non-over expressing invasive breast ca (Group 1) or invasive triple negative breast cancer (Group 2).</li> <li>• ER+ tumors should be Ki-67 index of 10% or greater.</li> <li>• ECOG 0-1</li> <li>• Local regional lymph node involvement is eligible but distant mets is excluded.</li> <li>• Measureable disease after biopsy – defined as 2 cm (T2, T3, or T4) by AJCC TNM Staging.</li> <li>• Must be willing to under go 2 mandatory core biopsies after tx</li> </ul>	<ul style="list-style-type: none"> <li>• Female patients only</li> <li>• No prior treatment for this cancer allowed including chemotherapy, surgery (biopsy allowed for diagnosis), hormonal therapy, radiation, or investigational agents.</li> <li>• LVEF &lt;55%</li> <li>• Must not Have a need for Chronic Steroid therapy</li> <li>• No Active Infections or unexplained fevers &gt;38.5°C during screening visits or day of dosing (tumor fever ok).</li> </ul>	<b>Enrolling</b>
<b>Breast Metastatic</b>	<b>BMS CA191011</b>  <b>Site #: 032</b>	<b>1<sup>st</sup>-2<sup>nd</sup> Line Phase II</b>  <b>Randomized / Open Label with Cross –Over Design</b>	<b>(Measurable Dz pt)</b> BMS-754807 ( <b>IGF-1R Tki</b> ) + Letrozole  Vs  BMS-754807 alone*  *Monotherapy pts alone can crossover at PD.  <b>(Non-Measurable Dz pt)</b> BMS-754807 + Letrozole	<ul style="list-style-type: none"> <li>• Postmenopausal ER+/PR+</li> <li>• HER2 negative disease</li> <li>• No more than 1 prior chemo regimen.</li> <li>• Subjects allowed to have failed multiple lines of hormonal tx.</li> <li>• Prior Tamoxifen is permitted.</li> <li>• Failed non-steroidal AI Tx.</li> <li>• ECOG 0-1</li> </ul>	<ul style="list-style-type: none"> <li>• No Diabetics</li> <li>• Must have Original tumor block available</li> <li>• Must be willing to undergo Tumor biopsy x 2 (in ATL)</li> <li>• PET Scans x 2 (in ATL)</li> <li>• FPG ≥ 7.0 mmol/L (126 mg/dl). One retest allowed.</li> </ul>	<b>Pending</b>
<b>Breast Metastatic</b>	<b>Celldex CDX011-03</b>  <b>EMERGE</b>  <b>Site #: 17</b>	<b>3<sup>rd</sup> – 8<sup>th</sup> line Phase II</b>  <b>Randomized</b>	CDX011 ( <b>Immunoconjugate</b> )  <b>Versus</b>  Investigators Choice Chemo (see protocol)*  *IC crosses over to CDX011 at progression.	<ul style="list-style-type: none"> <li>• <b>GPNMB overexpressed tumor (central testing)</b></li> <li>• Prior tx must include taxane, anthracycline, capecitabine, and for HER2+ pts trastuzumab / lapatanib</li> <li>• PD during / within 6 months of last tx</li> <li>• ECOG ≤ 1</li> </ul>	<ul style="list-style-type: none"> <li>• <b>No neuropathy &gt; grade 1</b></li> <li>• No symptomatic brain mets</li> <li>• Male or Female pts with locally adv or met dz (histologically or cytologically confirmed) BC</li> <li>• Received 2-7 prior regimens for metastatic or recurrent disease.</li> </ul>	<b>Enrolling</b>

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<b>GI</b>						
<b>Colorectal Metastatic</b>	SCRI GO27827 GI155	1 <sup>st</sup> Line Phase II Randomized Double-Blind Placebo-Controlled	MetMab (an Anti-MET MoAb) + FOLFOX/Avastin  Versus  Placebo + FOLFOX/Avastin	<ul style="list-style-type: none"> <li>Confirmed adenocarcinoma of colon or rectum with metastatic (Stage IV) disease.</li> <li>ECOG <math>\leq</math> 1</li> <li>Measurable Disease</li> <li>Confirmed availability of archived tissue (if no tissue available patient must be willing to undergo a biopsy)</li> </ul>	<ul style="list-style-type: none"> <li>No inadequately controlled Hypertension</li> <li>No &gt; Grade 1 Peripheral Neuropathy</li> <li>No Adjuvant chemotherapy (and/or chemo radiation) for colorectal carcinoma within 12 months prior to date of diagnosis of metastatic disease.</li> <li>Proteinuria at screening by urine dipstick if <math>\geq</math> 2+, patient must undergo a 24 hour urine. 24 Hour urine must be <math>\leq</math> 1 g to be eligible.</li> </ul>	<b>Enrolling</b>
<b>Colorectal Metastatic</b>	EISAI E7820 (MAX) Site #: 403	2 <sup>nd</sup> Line Phase Ib/II Randomized Open Label	Phase Ib: (@ NSO) Irinotecan & one of 3 ascending doses (40*, 70, or 100 mg) of E7820 (oral VEGF Inhibitor)  Phase II: Irinotecan & (MTD of E7820)  Versus  FOLFIRI	<ul style="list-style-type: none"> <li>Nonresectable locally advanced or metastatic colorectal adenocarcinoma</li> <li>Must have failed 1<sup>st</sup> line 5FU based regimens.</li> <li>Prior tx with Irinotecan or FOLFIRI not allowed.</li> <li>For Phase Ib only, up to 3 prior non-Irinotecan containing therapies are allowed (including adjuvant tx in addition to advanced disease.</li> <li>ECOG <math>\leq</math> 1</li> </ul>	<ul style="list-style-type: none"> <li>At least 1 site of measurable dz per RECIST V1.1</li> <li>No symptomatic brain mets</li> <li>No uncontrolled hypertension</li> <li>No peripheral neuropathy &gt;Gr2</li> <li>No hypersensitivity to Sulfonamide derivatives.</li> </ul>	<b>Enrolling @ NSO only Ph Ib</b>  *MTD complete
<b>LUNG</b>						
<b>SCLC Metastatic</b>	UAB 0818 Site #: none	1 <sup>st</sup> line Phase I/IIa Open Label	Bendamustine & Irinotecan x 3 cycles  <b>followed by</b>  Etoposide & Carboplatin x 3 cycles	<ul style="list-style-type: none"> <li>Histologic or cytologic diagnosis of extensive SCLC – defined as disease not confined to one hemithorax including ipsilateral pleural / pericardial effusion</li> <li>ECOG <math>\leq</math> 2</li> <li>Must be 18-79 y/o</li> </ul>	<ul style="list-style-type: none"> <li>No symptomatic brain mets</li> <li>No neuropathy <math>\geq</math> grade 2</li> <li>No chronic diarrhea; or diarrhea (excess of 2-3 stools/day above normal frequency in the past two weeks.</li> <li>No prior chemotherapy.</li> </ul>	<b>Enrolling</b>
<b>NSCLC Metastatic</b>	BiPar 20090321 (EFC11553) ECLIPSE Site #: 9029	1 <sup>st</sup> line Phase III Randomized Open Label	Gemzar & Carboplatin & Iniparib (aParp1Inhibitor)  Versus  Gemzar & Carboplatin	<ul style="list-style-type: none"> <li>Stage IV squamous NSCLC</li> <li>Prior adj tx completed <math>\geq</math> 12 months</li> <li>ECOG <math>\leq</math> 1</li> </ul>	<ul style="list-style-type: none"> <li>No prior treatment with Gemzar or Carboplatin unless in adjuvant setting</li> <li>No uncontrolled brain mets</li> <li>No prior treatment with Iniparib.</li> </ul>	<b>Enrolling</b>

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NSCLC Metastatic	Pfizer A8081014  PROFILE  Site#: 1013	1 <sup>st</sup> line  Phase III  Randomized  Statified (ECOG, Race, & Presence or Absence of Brain Mets)  Open Label	Crizotinib (c-MET / ALK- <b>tki inhibitor</b> )  <b>Versus</b>  Pemetrexed/ Cisplatin* OR Pemetrexed/ Carboplatin*  *Pts may be eligible for crossover at PD – if pt meets all screening eligibility criteria relevant to Crizotinib therapy.	<ul style="list-style-type: none"> <li>• Histologically or Cytologically proven dx of locally advanced not suitable for local treatment, recurrent and metastatic <b>non-squamous cell</b> carcinoma of the lung.</li> <li>• + translocation involving ALK gene (central testing)</li> <li>• No prior tx for metastatic disease. Prior adjuvant tx for Stage I-III or combined modality chemo/XRT for locall advanced dz allowed if completed &gt;12 months prior to randomization.</li> <li>• ECOG <math>\leq</math> 2</li> <li>• Must have measurable disease</li> </ul>	<ul style="list-style-type: none"> <li>• Brain mets are eligible only if treated and neurologically stable with no ongoing requirement of corticosteroids for at least 2 weeks.</li> <li>• No cord compression unless treated with pt attaining good pain control and stable neurologic function.</li> <li>• No carcinomatous meningitis or leptomeningeal disease.</li> <li>• No use of drugs or foods that are known potent CYP3A4 inhibitors, inducers, or substrates.</li> <li>• No Peripheral Neuropathy Grade <math>\geq</math> 1.</li> </ul>	<b>Enrolling</b>
NSCLC Metastatic	UAB 1021  Site #G	2 <sup>nd</sup> line  Phase II  Open Label Randomized Statified	Cabazitaxel XRP-6258 ( <b>Microtubule Inhibitor</b> )  <b>Schedule A:</b> 20 mg/m <sup>2</sup> Q 3 wks  Vs  <b>Schedule B:</b> 8.4 mg/m <sup>2</sup> D1,8,15,22 Q 5 wks	<ul style="list-style-type: none"> <li>• Histologic or cytologic diagnosis of NSCLC (<b>Squamous, Non-Squamous, or Non-Squamous – not Specified</b>)</li> <li>• Subjects who failed 1<sup>st</sup> line chemotherapy (Platinum or Non-Platinum Doublets [Previous Taxane exposure is allowed]) for Stage IV NSCLC.</li> <li>• Measurable disease per RECIST 1.1</li> <li>• ECOG 0-2</li> </ul>	<ul style="list-style-type: none"> <li>• No untreated Symptomatic Brain Mets</li> <li>• No <math>\geq</math> Grade 2 Neuropathy</li> <li>• At least 4 week washout from Major Surgery</li> <li>• At least 2 week washout from Previous Radiation</li> </ul>	<b>Enrolling</b>
NSCLC Metastatic	Daiichi ARQ197-A-U302  MARQUEE  Site #: 0119	2 <sup>nd</sup> or 3 <sup>rd</sup> line  Phase III  Randomized Double Blind/ Placebo Controlled	Erlotinib & Placebo  <b>Versus</b>  Erlotinib + ARQ 197 ( <b>c-MET inhibitor</b> )	<ul style="list-style-type: none"> <li>• Stage IIb-IV <b>NON SQUAMOUS</b> NSCLC</li> <li>• PD after 1 or 2 prior tx (one of which must have been platinum doublet)</li> <li>• PD after ADJ tx ok if tx completed &lt;6 months</li> <li>• ECOG <math>\leq</math> 1</li> </ul>	<ul style="list-style-type: none"> <li>• No prior tx w/ EGFR inhibitor, cMNGG protein, or cMet Inhibitor.</li> <li>• No uncontrolled brain mets</li> <li>• EGFR / KRAS confirmation by central lab prior to randomization</li> <li>• <math>\leq</math>Gr2 Neuropathy (CTC V4.0)</li> </ul>	<b>Enrolling</b>

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<b>PROSTATE</b>						
<b>Prostate PSA Risers Only</b>	<b>Johnson &amp; Johnson</b>  212082PCR2005  <b>IMAAGINE</b>  Site #: 001026	1 <sup>st</sup> line  Phase II  Open Label  Single Arm Study	Abiraterone ( <b>Inhibitor of CYP-17</b> ) & Prednisone  Abiraterone Acetate 1000 mg po once daily plus 5 mg Prednisone po daily.	<ul style="list-style-type: none"> <li>Prostate adenocarcinoma with <b>no</b> neuroendocrine or small cell histology</li> <li>Serum testosterone &lt;50ng/dL</li> <li>Rising PSA (PSA <math>\geq</math> 10 @ screening or PSADT of <math>\leq</math> 10 months with the first of the 3 baseline values being <math>\geq</math> 2 ng/ml.</li> <li>ECOG <math>\leq</math> 2</li> <li>Have a baseline K+ of <math>\geq</math>3.5 meq/l</li> <li>Must be capable of swallowing tablets</li> </ul>	<ul style="list-style-type: none"> <li><b>NO</b> prior or current evidence of local PD or metastatic disease</li> <li>No uncontrolled HTN</li> <li>No uncontrolled diabetes</li> <li>No flutamide within 4 weeks</li> <li>No bicalutamide or nilutamide within 6 weeks</li> <li>Subjects may not have previously received agents having any CYP17 inhibitory activity for the treatment of prostate cancer, such as Ketoconazole.</li> <li>No active infections or other medical condition that would contraindicate prednisone use.</li> <li>No history of pituitary or adrenal dysfunction</li> </ul>	<b>Enrolling</b>
<b>Prostate</b>	<b>Aragon</b>  ARN-509-001  Site #: 34	Non-Metastatic CRPC tx naïve (n=50)  Metastatic CRPC tx naïve (n=20) – <i>enrollment closed 11/21/11</i>  Metastatic CRPC Abiraterone tx'd for atleast 6 mo (n=10-20)  Phase II	ARN-509 ( <b>Anti-Androgen/ AR antagonist</b> ) oral medication  ARN-509 240 mg po daily	<ul style="list-style-type: none"> <li>Pts with mCRPC must have confirmed Ca w/o neuroendocrine or small cell features; with PD based on i) a rise in PSA, ii) CT scan, or iii) Bone Scan.</li> <li>Pts with non-metastatic CRPC must have confirmed Ca, as above, that is resistant to castration: i) PSA a minimum of 3 rising levels. Or ii) High risk for development – PSA <math>\geq</math> 8 ng/ml obtained no more than 3 months prior to enrollment, or PSADT <math>\leq</math> 10 months.</li> <li>ECOG 0-1 (2 is allowed only if due to bone pain)</li> </ul>	<ul style="list-style-type: none"> <li>Must continue Androgen depletion therapy with GnRH analogue or inhibitor.</li> <li>Testosterone &lt; 50 ng/dL w/I 4 weeks prior to D1.</li> <li>Bisphosphonate therapy must have been on stable doses for at least 4 weeks.</li> <li>Pts who are receiving a 1<sup>st</sup> generation anti-androgen (bicalutamide, flutamide, nilutamide) as 1<sup>st</sup> line hormonal therapy must show PD off the anti-androgen.</li> <li>4-wk washout needed for Androgen receptor antagonists (ie bicalutamide), 5-a reductase inhibitors (ie Ketoconazole)</li> <li>12 wk washout for Provenge (or immunotherapy).</li> </ul>	<b>Enrolling</b>

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<b>Prostate Metastatic</b>	<b>BMS CA184095</b>  <b>Site #: 049</b>	<b>1<sup>st</sup> line</b>  <b>Phase III</b>  <b>Randomized Double Blind/ Placebo Controlled</b>	Ipilimumab (CTLA-4 Inhibitor) 10 mg/kg q 3 wks x 4 f/b maintenance phase dose q 12 wks  <b>Versus</b>  Placebo 2 ml/kg at matching volume & frequency	<ul style="list-style-type: none"> <li>Asymptomatic or minimally asymptomatic (no opiate usage)</li> <li>Progression during hormonal tx defined as: <b>rising PSA or 2+ more lesions on BS or nodal progression on CT</b></li> <li>ECOG <math>\leq</math> 1</li> <li>Metastatic disease by CT, MRI, or Bone Scan.</li> </ul>	<ul style="list-style-type: none"> <li><b>NO visceral mets (liver, lung, brain)</b></li> <li>No bicalutamide, flutamide, ketoconazole within 4 wks</li> <li>No autoimmune diseases</li> <li><b>NO</b> prior chemotherapy, Provenge, or Radioisotope therapy.</li> <li>Not eligible if <math>\leq</math> 1 yr since resolution of <math>\geq</math> Grade 2 toxicity related to pelvic targeted therapy (e.g radiation enteritis)</li> <li>Prior malignancy w/i 3 yrs except locally curable cancers (such as basal or squamous cell skin cancer, superficial bladder cancer or carcinoma in situ of the breast).</li> </ul>	<b>Enrolling</b>
<b>PANCREATIC</b>						
<b>Pancreatic Metastatic</b>	<b>Abraxis CA046</b>  <b>Site #: 0980</b>	<b>1<sup>st</sup> line</b>  <b>Phase III</b>  <b>Open Label</b>	Gemzar  <b>Versus</b>  Gemzar + ABI-007 (Nab-Paclitaxel)	<ul style="list-style-type: none"> <li>Prior tx w/ Gemzar (cytotoxic) acceptable in adjuvant setting, however, Radiosensitizer type allowed with PD <math>\geq</math> 6 months after completion</li> <li>No prior tx for metastatic disease</li> <li>KPS <math>\geq</math> 70 (10% decrease b/w baseline &amp; randomization is not allowed.)</li> <li>Asymptomatic from jaundice and ascites prior to D1</li> <li>Stable pain without requiring modification of analgesics prior to D1</li> </ul>	<ul style="list-style-type: none"> <li>No islet cell neoplasms</li> <li>No uncontrolled brain mets (stable for <math>\geq</math> 3 months)</li> <li>No Coumadin</li> <li>Coagulation studies must be within acceptable ranges.</li> <li>Metastatic Dz must have occurred <math>\leq</math> 6 wks prior to randomization.</li> </ul>	<b>Enrolling</b>
<b>PHASE I</b>						
<b>Phase I Solid Tumor</b>	<b>ARQ 092-101</b>  <b>Site #:019</b>	<b>Phase I (Northside Only)</b>  <b>Dose Escalation Study</b>	<b>ARQ-092 (AKT Inhibitor)</b> – oral agent  MTD will be 10, 20, 40, 80, 120, 160, 220mg)  <u>Cohort 1:</u> (3 subject) Treatment will be initiated at a dose level of 10 mg every other day. DLT assessment @ 28 days. If no DLT start enrolling in Cohort #2.	<ul style="list-style-type: none"> <li>Histologically or cytologically documented, incurable, locally advanced or metastatic solid tumors in subjects who failed standard therapy or whom standard or curative therapy does not exist.</li> <li>Evaluable or measurable disease</li> <li>ECOG <math>\leq</math> 2</li> <li>Life expectancy &gt; 3 months</li> <li>Platelet count <math>\geq</math> 75,000</li> </ul>	<ul style="list-style-type: none"> <li>No history of Type 1 or 2 Diabetes Mellitus requiring regular medication (other than metformin)</li> <li>No prior treatment with AKT inhibitors.</li> <li>No Grade 2 or worse hypercholesterolemia or hypertriglyceridemia or &gt;8% glycated Hg (HGA1C)</li> <li>No Major surgery w/i 4 wks of 1<sup>st</sup> dose.</li> <li>No Anti-cancer chemotherapy, radiotherapy, immunotherapy, or investigational agents w/i 4 wks of</li> </ul>	<b>Enrolling</b>

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			(next dose level).		1 <sup>st</sup> dose of ARQ 092 (within 2 wks for oral drugs)	

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Phase I Solid Tumor	GSK EGF112930  Site #: 071469	Phase I (Northside Only)	Commercially available Lapatinib  Versus  Alternative Formulation of Lapatinib	<ul style="list-style-type: none"> <li>Her2+ Metastatic Breast</li> <li>Solid Tumors</li> <li>ECOG <math>\leq</math> 2</li> </ul>	<ul style="list-style-type: none"> <li>No uncontrolled brain mets</li> </ul>	On Hold
Phase I Solid Tumor	GSK EGF111767  Site #: 71468	Phase Ib	Lapatinib $\pm$ Chemotherapy (per table in protocol)	<ul style="list-style-type: none"> <li>Completed participation of GSK EGF112930 Phase I study at Northside Office</li> </ul>	<ul style="list-style-type: none"> <li>No discontinuation of Lapatinib in EGF112930 study due to intolerance or treatment failure</li> </ul>	On Hold
Phase I Multiple Myeloma	Immunomedics hLL1-DOX  Site #: 195	Phase I / II (Northside Only)	hLL1-DOX (Milatuzumab – Doxorubicin Antibody Drug Conjugate	<ul style="list-style-type: none"> <li>MM which is refractory / relapsed to <math>\geq</math> 2 prior tx (one tx must include thalidomide, lenalidomide or bortezomib)</li> <li>Karnofsky <math>\geq</math> 70%</li> <li>MM with 1 or more criteria for measurable dz: (serum M protein <math>\geq</math> 0.5 gm/dl, Urinary M Protein excretion <math>\geq</math> 200 mg/24hrs, serum free light chain measurement <math>&gt;</math> 20 mg/dl).</li> </ul>	<ul style="list-style-type: none"> <li>No patients who are eligible for stem cell transplant</li> <li>No cumulative anthracycline exposure <math>&gt;</math> 300mg/m<sup>2</sup></li> <li>No prior XRT to mediastinum or pericardium</li> <li>No persistent toxicity <math>\geq</math> gr 2</li> </ul>	Enrolling
Phase I/II MDS	GSK PMA112509  Site #: 058107	Phase I / II  Randomized Double Blind/ Placebo Controlled	Eltrombopag  Versus  Placebo	<ul style="list-style-type: none"> <li>Advanced MDS, sAML/MDS or de novo AML with <math>\geq</math> 10% and <math>\leq</math> 50% blasts in bone marrow.</li> <li>Subjects must be relapsed, refractory or ineligible to receive standard treatment options of Dacogen, Vidaza, and must be relapsed, refractory, or ineligible to receive intensive chemo or any type of transplant.</li> <li>Stable disease indicated by doubling time of peripheral blast counts <math>&gt;</math> 7 days during screening</li> <li>Platelet transfusion dependent OR platelet count <math>&lt;</math> 30 w/in 4wks prior to randomization</li> <li>ECOG <math>\leq</math> 3</li> </ul>	<ul style="list-style-type: none"> <li>No acute promyelocytic leukemia</li> <li>No prior treatment with NPlate or other TPO-R agonists</li> <li>No Leukocytosis <math>\geq</math> 25,000/uL prior to D1 of study medication</li> <li>No history of treatment of Cancer with systemic therapy or radiation w/i the last 2 yrs.</li> <li>No bone marrow fibrosis that leads to the inability to aspirate marrow for assessment.</li> <li>No Spleen <math>\geq</math> 14cm.</li> </ul>	Enrolling
<b>HEMATOLOGY</b>						
NHL	Millenium C05013  PYRAMID	1 <sup>st</sup> line  Phase II  Randomized	RCHOP  Versus  RCHOP + Velcade	<ul style="list-style-type: none"> <li>Untreated diffused large B cell lymphoma that has been subclassified as the non-GCB subtype</li> <li>ECOG <math>\leq</math> 2</li> <li>Must have a paraffin block with sufficient tumor tissue to allow</li> </ul>	<ul style="list-style-type: none"> <li>No CNS mets</li> <li>No grade <math>\geq</math> 2 neuropathy</li> </ul>	Enrolling

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	Site #: 074	Open Label		sufficient tumor tissue to allow for central testing. <ul style="list-style-type: none"> <li>• Must have at least 1 tumor measurable that is &gt; 1.5 cm in the long axis and &gt; 1.0 cm in the short axis.</li> </ul>		

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<b>NHL</b>	<b>GSK OMB110918</b>  <b>Site #: 067065</b>	<b>2<sup>nd</sup> line</b>  <b>Phase III</b>  <b>Randomized</b>  <b>Open Label</b>	Bendamustine + Ofatumumab ( <b>Human anti-CD20</b> )  <b>Versus</b>  Bendamustine   *Pts receiving Bendamustine alone will be allowed to received Ofatumumat at time of Progression.	<ul style="list-style-type: none"> <li>Small Lymphocytic, Lymphoplasmacytic, Marginal Zone Lymphoma, &amp; Follicular lymphoma (Gr: 1,2,&amp; 3A) verified to be CD20+ &amp; measurable lesions 2 or more with a largest diameter of 1.5cm, or 1 lesion with the largest diameter of <math>\geq 2.0</math>cm</li> <li>Indolent B-cell NHL stable or unresponsive during or w/in 6 months of tx with Rituxan</li> <li>ECOG <math>\leq 2</math></li> <li>Prior Bendamustine tx w/i a yr of randomization not resulting in a CR or PR for at least 6 months.</li> </ul>	<ul style="list-style-type: none"> <li>No aggressive lymphoma</li> <li>No previous allogenic stem cell transplant</li> <li>No autologous stem cell transplant, fludarabine tx or radioimmunotherapy w/in 6 months</li> <li>No prior XRT to pelvis, bony dz to the cranium, mediastinum, axilla, or to more than 3 vertebral bodies.</li> <li>No high dose steroid use <math>\geq 100</math>mg qd consecutively over 7 days, w/in 3 months, or 10 mg qd at time of randomization.</li> <li>No brain mets</li> </ul>	<b>Enrolling</b>
<b>ITP</b>	<b>IM-T-hA20-07</b>  <b>Site #: 195</b>	<b>Phase II</b>  <b>Open Label</b>	IMMU-106 (hA20) ( <b>Humanized anti- CD20 MoAb</b> )  -SQ dosing of 320 mg Q 2 wk for total of 2 injections.	<ul style="list-style-type: none"> <li>PLT <math>\leq 150,000</math> for <math>\geq 6</math> months</li> <li>1 prior standard ITP tx</li> <li>PLT <math>&lt; 30,000</math> at screening</li> <li>4 week stable dose of corticosteroid (<math>\leq 20</math>mg qd)</li> <li>Male/Female pt with or without prior splenectomy</li> </ul>	<ul style="list-style-type: none"> <li>No change in dose of danazol for 4 weeks</li> <li>Prior tx with Rituxan permitted, provided PR <math>\geq 6</math> months and last dose <math>\geq 12</math> months</li> </ul>	<b>Enrolling</b>
<b>Observation</b>	<b>Celgene MM</b>	<b>Observational</b>	Observational	<ul style="list-style-type: none"> <li>Newly diagnosed <b>and</b> symptomatic Multiple Myeloma within 2 months of enrollment into registry.</li> <li><math>\geq 18</math> years old</li> <li>Patient must agree to complete assessment questionnaires every 3 months.</li> </ul>	<ul style="list-style-type: none"> <li>No participation in a clinical trial where study treatment is blinded</li> </ul>	<b>Enrolling</b>
<b>Observation</b>	<b>Connect CLL</b>	<b>Observational</b>	Observational	<ul style="list-style-type: none"> <li>Confirmed CLL diagnosis</li> <li>Initiation of first-line, second-line, or subsequent line(s) of therapy within two months prior to enrollment in the Connect CLL Registry.</li> <li>Patient must agree to complete assessment questionnaires every 3 months.</li> </ul>	<ul style="list-style-type: none"> <li>No participation in a clinical trial where tx is blinded</li> <li>No patients with life expectancy <math>&lt; 6</math> months.</li> <li>No clinical diagnosis of small lymphocytic lymphoma (SLL) without the accompanying diagnosis of CLL.</li> <li>No Clinical diagnosis of prolymphocytic leukemia (PLL)</li> </ul>	<b>Enrolling</b>
<b>Observation</b>	<b>Allos PTCL</b>	<b>Observational</b>	Observational	<ul style="list-style-type: none"> <li>Newly diagnosed Peripheral T-Cell lymphoma</li> <li>Enrollment into registry within 30 days of starting tx for initial diagnosis of PTCL.</li> </ul>	<ul style="list-style-type: none"> <li>No Precursor T/NK neoplasms, T-cell large granular lymphocytic leukemia, mycosis fungoides, other than transformed mycosis fungoides, Sezary syndrome, Primary cutaneous CD30+ disorders: ALCL and</li> </ul>	<b>Enrolling</b>

